

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Re: Application of: Anand R. Baichwal  
Serial No.: Not yet assigned  
Filed: Herewith  
For: **SUSTAINED RELEASE MATRIX FOR HIGH-DOSE  
INSOLUBLE DRUGS**

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop: Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

December 9, 2003

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicant hereby makes of record the documents listed on the accompanying Form PTO-1449 (9 pages) for consideration by the Examiner in connection with the examination of the above-identified patent application.

The Examiner's attention is respectfully directed to pages 1 to 8 of the present Form PTO-1449, which are copies from Information Disclosure Statements filed during the prosecution of parent Application Serial Nos. 09/842,289; 09/420,247, now U.S. patent No. 6,245,355 and 08/889,424, now U.S. Patent No. 6,093,420.

The Examiner's attention is also directed to the 9th page of the Form PTO-1449 which lists U.S. Patent No. 5,330,761 and Remington's Pharmaceutical Sciences, references cited by the examiner during prosecution of the '247 Application.

Pursuant to 37 C.F.R. § 1.98(d), copies of these references of record in the parent applications are not enclosed. If it is determined that any of the listed references are not of record in the parent applications, the Examiner is requested to contact the undersigned so that a copy

can be forwarded.

Applicant also respectfully advises the Examiner of the following U.S. Patents and U.S. Applications which are commonly assigned to the owners of the instant application:

U.S. Patent No. 5,662,933, "Controlled Release Formulation (Albuterol)", issued September 2, 1997;

U.S. Patent No. 5,958,456, "Controlled Release Formulation (Albuterol)", issued September 28, 1999;

U.S. Patent No. 6,056,977, "Novel Once-A-Day Controlled Release Sulfonylurea Formulation", issued May 2, 2000;

U.S. Patent No. 6,537,578, "Novel Once-A-Day Controlled Release Sulfonylurea Formulation", issued March 25, 2003;

U.S. Patent Application Serial No. 10/396,114, "Novel Once-A-Day Controlled Release Sulfonylurea Formulation", filed March 25, 2003;

U.S. Patent No. 5,455,046, "Sustained Release Heterodisperse Hydrogel Systems for Insoluble Drugs", issued October 3, 1995;

U.S. Patent No. 5,512,297, "Sustained Release Heterodisperse Hydrogel Systems for Insoluble Drugs", issued April 30, 1996;

U.S. Patent No. 5,554,387, "Sustained Release Heterodisperse Hydrogel Systems for Insoluble Drugs", issued September 10, 1996;

U.S. Patent No. 5,667,801, "Sustained Release Heterodisperse Hydrogel Systems for Insoluble Drugs", issued September 16, 1997;

U.S. Patent No. 5,846,563, "Sustained Release Heterodisperse Hydrogel Systems for Insoluble Drugs", issued December 8, 1998;

U.S. Patent No. 6,136,343, "Sustained Release Heterodisperse Hydrogel Systems for Insoluble Drugs", issued October 24, 2000;

U.S. Patent Application No. 09/654,691, "Sustained Release Heterodisperse Hydrogel Systems for Insoluble Drugs", filed September 5, 2000;

U.S. Patent No. 5,773,025, "Sustained Release Heterodisperse Hydrogel Systems-Amorphous Drugs", issued June 30, 1998;

U.S. Patent No. 6,048,548, "Sustained Release Heterodisperse Hydrogel Systems-Amorphous Drugs", issued April 11, 2000; and

U.S. Patent No. 6,245,356, "Sustained Release Heterodisperse Hydrogel Systems-Amorphous Drugs", issued June 12, 2001;

U.S. Patent Application No. 09/879,296, "Sustained Release Heterodisperse Hydrogel Systems-Amorphous Drugs", filed June 12, 2001;

This Information Disclosure Statement is filed under 37 C.F.R. §1.97 (c), after the period specified in 37 C.F.R. §1.97 (b) but before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R § 1.311. Accordingly, enclosed is a check for \$180.00 in satisfaction of the fee due under 37 C.F.R. § 1.17 (p).

It is respectfully requested that the references cited in the accompanying Form PTO-1449 be considered and made of record. It is respectfully submitted that the pending claims are patentable over all of the references made of record at this time.

In the event any additional fee is due in connection with this response or if any fee has been overpaid, the deficiency or overpayment should be charged to our Deposit Account No. 50-0552.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 

Cary S. Kappel  
Reg. No. 36,561

DAVIDSON, DAVIDSON & KAPPEL, LLC  
458 Seventh Avenue, 14<sup>th</sup> floor  
New York, New York 10018  
(212) 736-1940

<b>PATENT AND TRADEMARK OFFICE</b>  <b>LIST OF REFERENCES CITED BY APPLICANT</b>  (Use several sheets if necessary)	<b>ATTY. DOCKET No.</b> 540.1020CON3	<b>SERIAL NO.:</b> To be Assigned
	<b>APPLICANT:</b> Anand R. Baichwal	
	<b>FILING DATE:</b> Herewith	<b>GROUP:</b> To be Assigned

### U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER								DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	4	8	0	3	0	8	1	2/7/89	Falk, et al.	424	488	
	AB	4	8	9	4	2	3	5	1/16/90	Kohne, et al.	424	452	
	AC	5	1	0	8	7	5	7	4/28/92	Erdos, et al.	424	451	
	AD	5	5	5	4	3	8	7	9/10/96	Baichwal	424	488	
	AE	4	1	9	1	7	7	2	3/4/80	Woog, et al.	424	273R	

### FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER								DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	
													YES	NO
	AF	8	5	0	4	1	0	0	9/26/85	PCT A1	A61K	9/40	X	
	AG	9	4	2	3	7	0	0	10/27/94	PCT A1	A61K	9/16	X	
	AH	2	7	1	4	0	6	5	10/12/78	Germany A1	A61K	9/10	Abstract	
	AL	3	4	0	0	1	0	6	7/11/85	Germany A1	A61K	9/00	Abstract	

### OTHER REFERENCES CITED (Including Author, Title, Date, Pertinent Pages, Etc.)

	AJ	Chemical Abstracts, Vol. 104 (1986) Abstract 174662y
	AK	Chemical Abstracts, Vol. 99 (1983) Abstract 128360d
	AL	Chemical Abstracts, Vol. 92 (1980) Abstract 135278s
	AM	Chemical Abstracts, Vol. 92 (1980) Abstract 82429h
	AN	Chemical Abstracts, Vol. 77 (1972) Abstract 39130g
	AO	Chemical Abstracts, Vol. 70 (1969) Abstract 17133p
	AP	Chemical Abstracts, Vol. 98 (1983) Abstract 221832y
	AQ	Alderman, D.A., "A review of cellulose ethers in hydrophilic matrices for oral controlled-release dosage forms", <u>Int. J. Pharm. Tech. &amp; Prod. Mfg.</u> , Vol 5, pages 1-9 (1984)
	AR	Haynes, R. Brian, M.D., et al., "Manipulation of the therapeutic regimen to improve compliance: Conceptions and misconceptions", <u>Clinical Pharmacology and Therapeutics</u> , Vol. 22, No. 2, (August 1977)
	AS	English translation of Japanese Patent Laid-Open-To-Public, publication no. 8/1986, publication date 1/6/86, Japanese Patent Application No. 118,789/1984; Japanese Patent Application date: 6/9/84
	AT	<u>Techniques of Solubilization of Drugs</u> , edited by Samuel H. Yalkowsky, The Upjohn Company, pub. Marcel Dekker, Inc., New York and Basel, pages 308-315 (1981)

EXAMINER	DATE CONSIDERED
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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<b>U.S. PATENT DOCUMENTS</b>																			
*EXAMINER INITIAL	DOCUMENT NUMBER								DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE						
	BA	3	4	8	5	8	4	7	12/23/69	Bossert, F., et al.	260	295.5							
	BB	3	7	8	4	6	8	4	1/8/74	Bossert, F., et al.	424	37							
	BC	4	6	6	5	0	8	1	5/12/87	Doi, et al.	514	356							
	BO	4	8	8	6	7	2	3	12/26/89	Kim, et al.	424	450							
	BE	4	9	8	3	5	9	3	1/8/91	Miyajima, et al.	514	110							
<b>FOREIGN PATENT DOCUMENTS</b>																			
	DOCUMENT NUMBER								DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION						
													YES	NO					
	BF	9	3	1	3	7	7	3	7/22/93	WO (A1)	A61K	31/44	X						
	BG	0	0	4	7	8	9	9	3/24/82	EPO (A1)	A61K	9/14	Abstrac						
	BH	0	1	4	7	1	7	1	7/3/85	EPO (A2)	C07D	401/12	X						
	BI	2	1	0	1	6	8	0	2/6/94	Canada (A1)	A61K	31/44	X						
<b>OTHER REFERENCES CITED (Including Author, Title, Date, Pertinent Pages, Etc.)</b>																			
	BJ	"Crystallization and Granulation", Remington's Practice of Pharmacy, 9th Ed. Chapter XXVII, pages 208-211, 1950																	
	BK	Ritschel, Angewandte Blopharmazie, pages 293-302 (1973)																	
	BL	Sugimoto, I., et al., "Dissolution and Absorption of Nifedipine From Nifedipine-Polyvinylpyrrolidone Coprecipitate", <u>Drug Development and Industrial Pharmacy</u> , Vol. 6, No. 2, pages, 137-161 (1980).																	
	BM	Kleinbloem, M., et al., Nifedipine: Kinetics and dynamics in healthy subjects", <u>Chin. Pharmacol. Ther.</u> , Vo. 35, No. 6, pages 742-749 (1984)																	
	BN	Ramasch, K., et al., "Pharmacokinetics and Metabolism of Nifedipine", <u>Hypertension Supplement II</u> , Vo. 5, No. 4, July-August 18-24 (1983)																	
	BO	McGinity, J.W., et al., "Dissolution and Uniformity Properties of Ordered Mixes of Micronized Griseofulvin and a Directly Compressible Excipient", <u>Drug Development and Industrial Pharmacy</u> , Vol. 11, No. 4, Pages 891-900 (1985)																	
	BP	Helbig, J., et al. "Pharmaceutical oral dosage forms of an active agent capable of forming or releasing bicarbonate ions", <u>Pharmaceuticals</u> , (Abstract-98:221837d), vol. 98, page 63 (1983)																	
	BQ	The Merck Index, pages 848-849, 9th Ed. (1976)																	
	BR	D.Q.M.Craig, "Polyethylene Glycols and Drug Release", <u>Drug Development and Industrial Pharmacy</u> , 16(17), Pages 2501-2526 (1990)																	
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*EXAMINER INITIAL	DOCUMENT NUMBER								DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	CA	5	0	1	5	4	7	9	5/14/91	Mulligan, et al.	424	457	
	CB	5	1	2	8	1	4	2	7/7/92	Mulligan, et al.	424	457	
	CC	5	1	1	0	6	0	2	5/5/92	Kim, et al.	424	451	
	CD	5	1	6	0	7	3	4	11/3/92	Ganesan, et al.	424	78.38	
	CE	5	2	6	4	4	4	9	11/23/93	Hegasy, et al.	514	356	
	CF	4	4	1	2	9	8	6	11/1/83	Kawata, et al.	424	80	
	CG	4	5	6	2	0	6	9	12/31/85	Hegasy, et al.	424	80	
	CH	4	6	7	3	5	6	4	8/16/88	Kawata, et al.	424	494	
	CI	4	7	6	4	3	8	2	8/16/88	Kydonieus, et al.	424	449	
	CJ	4	7	6	5	9	9	0	8/23/88	Sugimoto, et al.	424	494	
	CK	4	7	9	2	4	5	0	12/20/88	Kydonieus, et al.	424	449	
	CL	4	7	9	2	4	5	2	12/20/88	Howard, et al.	424	475	
	CM	4	8	0	8	4	1	3	2/28/89	Joshi, et al.	424	458	
	CN	4	8	5	1	2	2	9	7/25/89	Magruder, et al.	424	457	
	CO	4	8	6	7	9	8	5	9/19/89	Heafield, et al.	424	461	

  

FOREIGN PATENT DOCUMENTS														
	DOCUMENT NUMBER								DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	
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CP	2	1	6	0	1	0	0	12/18/95	Great Britain (A)	A61K	9/22	X		
CQ														

  

OTHER REFERENCES CITED (Including Author, Title, Date, Pertinent Pages, Etc.)													
	CR												
	CS												
	CT												

  

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*EXAMINER INITIAL	DOCUMENT NUMBER								DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE		
	DA	5	4	3	9	6	8	7	8/8/95	Compassi	424	468			
	DB	5	4	7	6	6	5	4	12/19/95	Conte, et al.	424	78.08			
	DC	4	8	9	2	7	4	1	1/9/90	Ohm, et al.	424	479			
	DD	4	9	0	4	8	9	9	2/27/90	Bauer	514	972			
	DE	4	9	4	0	5	8	7	7/10/90	Jenkins, et al.	424	480			
	DF	4	9	4	2	0	4	0	7/17/90	Ragnarsson, et al.	424	486			
	DG	4	9	7	3	4	6	9	11/27/90	Mulligan, et al.	424	461			
	DH	4	9	9	4	2	7	6	2/19/91	Baichwal, et al.	424	440			
	DI	5	0	0	7	7	9	0	4/16/91	Shell	424	451			
	DJ	5	0	1	9	3	9	7	5/28/91	Wong, et al.	424	473			
	DK	5	0	5	1	2	6	3	9/24/91	Barry, et al.	424	490			
	DL	5	0	7	1	6	4	2	12/10/91	Lahr, et al.	424	474			
	DM	5	1	2	8	1	4	3	7/7/92	Baichwal, et al.	424	464			
	DN	5	1	3	2	1	1	6	7/21/92	Soumac, et al.	424	469			
<b>FOREIGN PATENT DOCUMENTS</b>															
	DOCUMENT NUMBER								DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION		
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	DO	0	2	3	2	1	5	5	8/12/97	EP (A2)					
	DP	0	3	5	7	7	9	3	3/14/90	EP (A1)					
	DQ	W O	89	0	2	7	3	8	4/6/89	PCT					
	DR	W O	92	0	6	6	8	0	4/30/92	PCT					
	DS	1	2	8	8	0	4	9	8/27/91	Canada					
<b>OTHER REFERENCES CITED (Including Author, Title, Date, Pertinent Pages, Etc.)</b>															
	DJ														
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## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER								DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	EA	5	1	3	3	9	7	4	7/28/92	Paradissis, et al.	424	480	
	EB	5	1	3	5	7	5	7	8/4/92	Baichwal, et al.	424	465	
	EC	5	1	4	5	6	8	3	9/8/92	Rhodes	424	451	
	ED	5	1	6	9	6	3	8	12/8/92	Dennis, et al.	424	457	
	EE	5	2	1	5	7	5	8	6/1/93	Krishnamurthy	424	488	
	EF	5	2	6	4	4	5	9	11/23/93	Chelmick-Schorr, et al.	514	646	
	EG	5	2	7	3	7	6	0	12/28/93	Ohslack, et al.	424	480	
	EH	5	2	8	6	4	9	3	2/15/94	Oshlack, et al.	424	468	
	EI	5	3	5	6	4	6	7	10/18/94	Oshlack, et al.	106	153	
	EJ	5	4	5	5	0	4	6	10/3/1995	Baichwal	424	457	

## FOREIGN PATENT DOCUMENTS

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	EK	0	2	3	4	6	7	0	2/9/87	EP (B1)				
	EL													
	EM													
	EN													

## OTHER REFERENCES CITED (Including Author, Title, Date, Pertinent Pages, Etc.)

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		FA	4	7	6	5	9	8	9	8/23/88		Wong, et al.			424		473			
		FB	4	8	8	0	6	2	3	11/14/89		Piergiorgio, et al.			424		78			
		FC	5	1	6	9	6	3	9	12/8/92		Baichwal			424		458			
		FD	5	0	9	1	1	9	0	2/25/92		Kuczynski, et al.			424		473			
		FE	5	6	6	7	8	0	1	9/16/97		Baichwal			424		457			
		FF	5	8	6	2	9	3	3	9/2/97		Baichwal, et al.			424		457			
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		FH	5	7	7	3	0	2	5	6/30/98		Baichwal			424		458			
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	GG	4	0	0	0	8	1	5	9/29/87	Schepky, et al.	424	80							
	GH	5	2	1	1	9	5	7	5/18/93	Hagemann, et al.	424	466							
	GI	5	2	8	0	5	0	0	2/22/94	Ibsen	424	489							
	GJ	5	2	0	2	5	3	4	3/8/94	Valentine, et al.	424	451							
	GK	5	4	7	2	7	1	1	12/5/95	Baichwal	424	468							
	GL	5	4	7	8	5	7	4	12/26/95	Baichwal, et al.	424	485							
	GM	5	0	4	0	5	6	3	12/8/98	Baichwal	424	457							
	GN	5	5	4	3	0	9	9	3/6/96	Zhang, et al.	264	115							
<b>FOREIGN PATENT DOCUMENTS</b>																			
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	GQ																		
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FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
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	IA	5	3	3	0	7	6	1	July 1994	Baichwal	424	469	
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		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	II	1	3	1	3	1	3	3	1/26/93	Canada	A61k	9/22		
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	IN	2	1	3	1	6	4	7	08/10/99	Canada	A61k	9/22		
	IO	2	0	3	4	0	9	6	07/16/91	Canada	A61k	31/19		
	IP													

**OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)**

	IR	Remington's Pharmaceutical Sciences, 18 <sup>th</sup> edition, Mack Publishing Company, 1990, pp 1634
	IS	
	IT	

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